

**REMARKS**

Reconsideration of this application, as amended, is respectfully requested. Claims 1, 2, 4, 9 and 15-19 have been amended without prejudice or disclaimer to further clarify the invention. Claim 3 has been cancelled without prejudice or disclaimer. Applicants reserve the right to prosecute all subject matter in this application, including amended or cancelled claims, in a continuation application. New claims 20-28 have been inserted. Applicants maintain that the new claims are supported by the instant application as originally filed. With this amendment, claims 1, 2, and 4-28 are currently pending in this application. Consideration and entry of this response is respectfully requested.

**DOCKET NUMBER**

Applicants respectfully request that the docket number for this application be changed from 13115 to "API-02-06-US", if possible. Applicants appreciate the Examiner's assistance with this request.

**INFORMATION DISCLOSURE STATEMENTS**

Applicants submitted an Information Disclosure Statement (IDS) on Nov. 1, 2001 and a second IDS on Feb. 5, 2002. Applicants do not have a copy of the signed PTO-1449 for either submission in their files. Applicants respectfully request the Examiner to provide a copy of the signed PTO-1449 forms for their records. If such copies have been previously provided to Applicants, Applicants apologize for any inconvenience this may cause the Examiner.

**REJECTIONS UNDER 35 U.S.C. 112, SECOND PARAGRAPH**

Claims 4-16 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. Applicants have amended the claims such that the term "nucleic acid" has antecedent basis. As such, Applicants respectfully request withdrawal of this rejection.

**REJECTIONS UNDER 35 U.S.C. 102(b)**

Claims 1-4, 9-10 and 16-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Dalemans (WO 99/30733). Applicants respectfully traverse the rejection as indicated below.

The Examiner alleges that Dalemans teaches a prime boost strategy at page 28, claims 1-13 and at page 29, claims 19-24. In addition, the Examiner alleges that Dalemans teaches the administration of a nucleic acid and a peptide to the spleen or lymph tissue associated with the skin. Thus, the Examiner alleges, Dalemans anticipates the instantly claimed invention. Applicants respectfully disagree, as indicated below.

With respect to Dalemans' claims 1-13, both of the independent claims (claims 1 and 8) refer to the "simultaneous administration" of a polynucleotide encoding a polypeptide and the polypeptide itself. Applicants respectfully maintain that this is distinct from the instantly claimed prime-boost strategy as stated by the Dalemans reference itself at, for example, page 4, lines 25-28.

Dalemans' claims 19-24 relate to a vaccine (i.e., claims 19-22) or composition (i.e., claims 23-24) comprising DNA and polypeptide in a single composition. One of skill in the art would understand that the DNA and the polypeptide are prepared together in a single composition. For example, claim 19 refers to "the ratio of DNA:Polypeptide is from 1000:1 to 1:1 (w/w)" and claims 23 and 24 refer to DNA and polypeptide being "admixed together". In contrast, the instantly claimed method relates to at least two different compositions, that used in the priming step and that used in the boosting step.

In addition, Dalemans is completely silent as to intranodal immunization, as instantly claimed. Applicants respectfully maintain that one of skill in the art would understand "skin associated lymphoid tissues" to be distinct from lymph nodes.

For the reasons stated above, Applicants respectfully maintain that the instant claims are not anticipated by Dalemans. As such, it is requested that these rejections be withdrawn.

**REJECTIONS UNDER 35 U.S.C. 103(a)****A. REJECTION OF CLAIMS 1, 2, 4-14 AND 16-17**

Claims 1, 2, 4-14, 16 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hurpin (Vaccine, 16(2/3): 208-215, 1998) in view of Hodge (Vaccine, 15(6/7): 759-768, 1997). Applicants respectfully traverse this rejection as indicated below.

Applicants maintain that both Hurpin and Hodge are completely silent as to administration of an antigen to a lymph node. As such, neither Hurpin nor Hodge, alone or in combination, are proper references upon which a 35 U.S.C. 103(a) rejection of the instant claims may be based. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**B. REJECTION OF CLAIMS 1 AND 17-19**

Claims 1, and 17-19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hurpin in view of Hodge, Zaremba (Cancer Res. 57: 4570-4577, 1997), and Salgaller (Cancer Res. 56: 4749-4757, 1996). Applicants respectfully traverse this rejection as indicated below.

As described above, both Hurpin and Hodge are completely silent as to intranodal immunization. As such, neither Hurpin nor Hodge, alone or in combination, are proper references upon which a 35 U.S.C. 103(a) rejection of the instant claims may be based. Applicants maintain that neither Zaremba nor Salgaller, correct the deficiencies of Hurpin and/or Hodge. In addition, neither Zaremba nor Salgaller, alone or in combination with one another, Hurpin and/or Hodge, provide a proper basis upon which a 35 U.S.C. 103(a) rejection of the instant claims may be based. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**CONCLUSIONS**

Consideration and entry of this amendment is respectfully requested. Applicants respectfully maintain that claims 1, 2 and 4-28 are now in condition for allowance and request that a Notice of Allowance for the pending claims. If the Examiner has any questions or believes a discussion would expedite prosecution, he is encouraged to contact the undersigned at 570-839-5446.

Respectfully submitted,

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Date: September 5, 2003

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